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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/815,930	04/02/2004	Chien-Hsuan Han	022424-003300US	9425

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EXAMINER	
AHMED, HASAN SYED	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 10/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/815,930	HAN ET AL.	
	Examiner	Art Unit	
	Hasan S. Ahmed	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-56* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-12, drawn to a pharmaceutical dosage form comprising an immediate release and an enteric-coated controlled release component wherein: (a) the immediate release component exhibits a dissolution profile comprising at least about 80% $GABA_B$ agonist release after 1 hour, and (b) the enteric-coated controlled release component exhibits a dissolution profile comprising at least about 40% $GABA_B$ agonist release after 1 hour, and at least about 70% $GABA_B$ agonist release after 4 hours, classified in class 424, subclass 451.

II. Claims 13-24, drawn to a pharmaceutical dosage form comprising an immediate release and an enteric-coated controlled release component wherein: (a) the immediate release component exhibits a dissolution profile comprising at least about 80% $GABA_B$ agonist release after 1 hour, and (b) the enteric-coated controlled release component exhibits a dissolution profile comprising at least about 10% $GABA_B$ agonist release after 2 hour, at least about 40% $GABA_B$ agonist release after 3 hours, and at least about 70% $GABA_B$ agonist release after 6 hours, classified in class 424, subclass 451.

III. Claims 25-40, drawn to a pharmaceutical dosage form comprising a $GABA_B$ agonist and excipient – exhibiting a plasma profile comprising

mean maximum $GABA_B$ agonist release from about 30 minutes to about 7 hours after administration to a fasting patient – classified in class 424, subclass 451.

IV. Claims 41-56, drawn to a pharmaceutical dosage form comprising a $GABA_B$ agonist and excipient – exhibiting a plasma profile comprising at least two hours of sustained $GABA_B$ agonist concentrations at greater than therapeutic levels – classified in class 424, subclass 451.

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The inventions are distinct, each from the other for the following reasons:

Inventions I and II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the dosage form of Group I claims a dissolution profile not required by Group II. The subcombination has separate utility such as use in a depot formulation.

Inventions I and III are related as combination and subcombination. In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the dosage form of Group I claims a dissolution profile not required by Group III. The subcombination has separate utility such as use in a depot formulation.

Inventions I and IV are related as combination and subcombination. In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the dosage form of Group I claims a dissolution profile not required by Group IV. The subcombination has separate utility such as use in a depot formulation.

Inventions II and III are related as combination and subcombination. In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the dosage form of Group II claims a dissolution profile not required by Group III. The subcombination has separate utility such as use in a depot formulation.

Inventions II and IV are related as combination and subcombination. In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the dosage form of Group II claims a dissolution profile not required by Group IV. The subcombination has separate utility such as use in a depot formulation.

Inventions III and IV are related as combination and subcombination. In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the dosage form of Group III claims a plasma profile not required by Group IV. The subcombination has separate utility such as use in a depot formulation.

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Because these inventions are independent or distinct for the reasons given

above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

The examiner has required restriction between combination and subcombination inventions. Where applicant elects a subcombination, and claims thereto are subsequently found allowable, any claim(s) depending from or otherwise requiring all the limitations of the allowable subcombination will be examined for patentability in accordance with 37 CFR 1.104. See MPEP § 821.04(a). Applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

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This application contains claims directed to the following patentably distinct species:

Group I

- Species I - Election of baclofen optical isomer in claims 5 and 6:
    a. Racemic mixture (claim 5)
    b. L-enantiomer of baclofen (claim 6)
- Species II - Election of formulation in claims 10 and 11:
    a. Tablet (claim 10)
    b. Capsule (claim 11)

Group II

- Species I - Election of baclofen optical isomer in claims 17 and 18:
    a. Racemic mixture (claim 17)
    b. L- enantiomer of baclofen (claim 18)
- Species II - Election of formulation in claims 22 and 23:
    a. Tablet (claim 22)
    b. Capsule (claim 23)

Group III

- Species I - Election of baclofen optical isomer in claims 33 and 34:
    a. Racemic mixture (claim 33)
    b. L- enantiomer of baclofen (claim 34)
- Species II - Election of formulation in claims 38 and 39:
    a. Tablet (claim 38)
    b. Capsule (claim 39)

Group IV

- Species I - Election of baclofen optical isomer in claims 49 and 50:
    a. Racemic mixture (claim 49)
    b. L- enantiomer of baclofen (claim 50)
- Species II - Election of formulation in claims 54 and 55:
    a. Tablet (claim 54)
    b. Capsule (claim 55)

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Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 11, 21, and 34 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

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Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should Applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

☆

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hasan S. Ahmed whose telephone number is 571-272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MICHAEL P. WOODWARD
SUPERVISORY PATENT EXAMINER
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